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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,500	12/12/2005	Michael Tolar Martin	PR60328USW	3197
23347	7590	02/25/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 02/25/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LAURA.M.MCCULLEN@GSK.COM

Office Action Summary	Application No. 10/560,500	Applicant(s) MARTIN ET AL.	
	Examiner Joseph R. Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-24 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-7, 10-14, 17-20 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-3, 15, 16, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-7 and 10-24 are pending in the instant application.

Priority

The claim to priority as a 371 filing of PCT/US04/20353 filed June 25, 2004, which claims priority to 60/483,002 filed June 27, 2003 is acknowledged in the instant application.

Information Disclosure Statement

The information Disclosure Statement filed on December 12, 2005 has been considered by the Examiner with the exception of the NPL which has not been considered due to failure to provide a copy of the reference. The document that was not considered has been lined out in the returned 1449 form.

Claim Rejections - 35 USC § 102

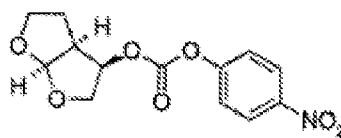
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

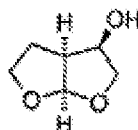
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sham et al. (WO 97/21683 A1).

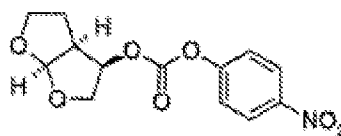
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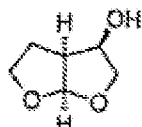
The claims are drawn to the compound and a



process of making the compound by reacting with 4-nitrophenyl chloroformate in a suitable solvent.



Sham et al. teaches a process to make by



reacting and 4-nitrophenyl chloroformate in methylene chloride. See page 65, step C of Example 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

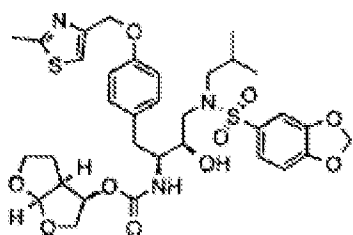
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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

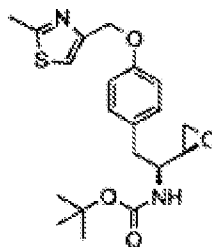
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hale et al. (WO 00/76961 A1) in view of Sham et al. (WO 97/21683 A1).

The instant claims are drawn to a process of making

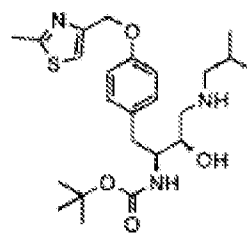



by: treating

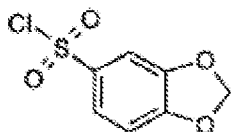


with excess

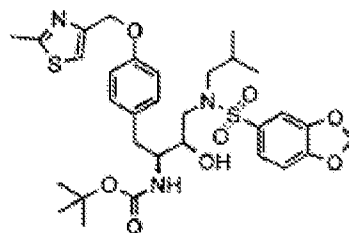
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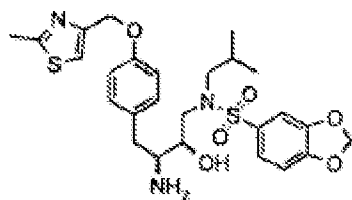
isobutylamine in an alcohol-containing solvent to form , then



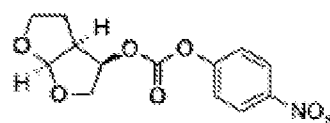
treating with  in the presence of an aqueous or non-aqueous



base to form , then deprotecting the compound to

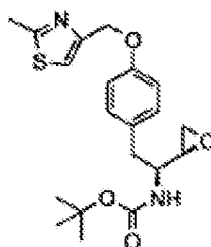


form , then coupling with



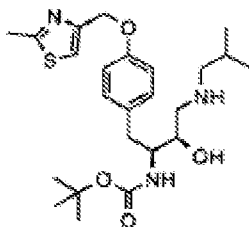
form the desired compound.

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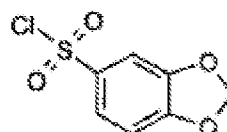
Hale et al. teach the process

with isobutylamine in

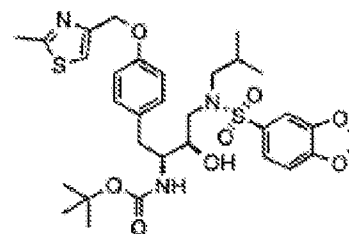


ethanol to form

, then adding

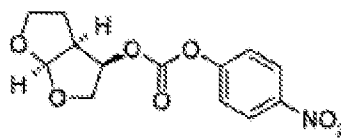


in the

presence of $i\text{Pr}_2\text{NEt}$ and methylene chloride to form

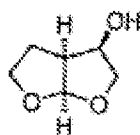
followed by deprotection by TFA and then coupling to an acyl halide. See pages 56-59, Schemes 1-3 and pages 306-307, Example 152 for the final product.

Hale et al. do not teach the use of an aqueous base, the combination of steps a and b or c and d in a one pot reaction, or the specific solvent combination or aqueous base used in claims 23 or 24.



Sham et al. teaches a process to make

by

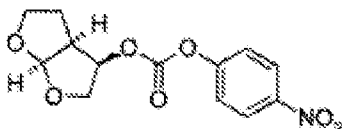


reacting

and 4-nitrophenyl chloroformate in methylene chloride. See

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page 65, step C of Example 4. As para-nitrophenolate is an art-recognized leaving group, it would be in the perview of one of ordinary skill to replace an acyl



chloride with . Additionally, changing what base is used or what solvent is used or combining steps into one pot in a reaction is routine optimization. The person of ordinary skill in the art, which in the instant case is a synthetic chemist, is always looking for ways to make a reaction run smoother, quicker, and with higher yield in order to more efficiently obtain desired compounds. Therefore, the claims are *prima facie* obvious over the prior art.

Conclusion

Claims 1-3, 15-16, 21, and 23-24 are rejected. Claims 4-7, 10-14, 17-20, and 22 are currently allowable over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626